PATENT APPLICATION

OF

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FOR

IMPLANTABLE PUMP APPARATUSES

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IMPLANTABLE PUMP APPARATUSES

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of application serial number 09/586,962, filed on 6/5/2000, now U.S. Patent number 6,589,198, which is a continuation in part of application serial number 09/015,759, filed on 1/29/98, now U.S. Patent number 6,168,575.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to pump assemblies. More specifically, it relates to micro-miniature pumps which may be used as bio-compatible medical implants for controlling diseases such as glaucoma.

DESCRIPTION OF THE PRIOR ART

Mechanical and electro-mechanical medical implants are well known, and, depending upon the type, have met with varying success rates. One problem with these devices is the lack of a reliable, long term power source. Ideally, the power source should last for the life of the implant, as many of these implants require invasive procedures both to install and

maintain. Indeed, an external power source is virtually impossible in many situations, making the use of internal, self contained power sources highly preferable.

One use for mechanical implants is the treatment of glaucoma. Glaucoma is a common eye disease which is caused by excessive ocular pressure in the anterior chamber of the eyeball. Many devices and techniques have been devised in order to control this pressure. The devices fall generally into two types; passive devices such as a simple tubular shunt or similar device which drains aqueous humor from the anterior chamber, and active devices which have means for controllably draining ocular pressure by pumping out a small amount of aqueous humor, the systems typically using check valves or similar mechanical devices to regulate pump action. While these systems are somewhat effective, they tend to suffer from the drawback in that they are unreliable or require frequent maintenance which always involves a fairly invasive procedure. Failure to properly maintain the devices can result in long term damage to surrounding tissue especially in the case of pumps used to control glaucoma.

United States Patent No. 5,370,607 issued to Memmen discloses a glaucoma implant device which has a tubular shunt for draining fluid from the eye.

United States Patent No. 4,911,616 issued to Laumann, Jr. discloses a microminiature pump which may be used to administer medications in sensitive locations in the body such as the eye. The pump is programmable, but the patent does not disclose which aspects of the pump operation can be controlled.

United States Patent No. 5,062,841 issued to Siegel discloses an insulin pump which can be used to pump insulin directly into the bloodstream in response to blood glucose levels.

United States Patent No. 5,433,701 issued to Rubinstein discusses an active ocular pressure control device which, in one embodiment, includes a pump which is selectively operated in response to a control signal from a pressure sensor.

The present invention contemplates a pumping system which utilizes a flexible, pressure reactive bladder as the primary actuator.

SUMMARY OF THE INVENTION

The present invention concerns an implantable, miniature pump assembly having a flexible bladder actuating assembly. The bladder, in the non-flexed state, has an elongated, substantially rectangular profile, with a predetermined internal volume or capacity. Influent and effluent conduits extend in opposite directions from respective end portions of the bladder. Each of the conduits include one way valves disposed therein to limit fluid flow to a single direction into and through the bladder. Expansion of the bladder in response to ambient conditions creates a temporary vacuum within the bladder, drawing fluid into the bladder through the influent conduit, whereas contraction of the bladder forces fluid from the bladder via the effluent conduit.

Accordingly, it is a principal object of the invention to provide a self powered pump

employing a flexible bladder as the primary actuator.

It is a major object of this invention to provide a family of implantable pump assemblies having a common actuator mechanism, the size and shape of the pump and the actuator mechanism selected in accordance with a predetermined function.

It is another object of this invention to provide a family of implantable pump assemblies having an elastic bladder actuator which is powered by environmental disturbances which create local pressure variations.

It is another object of the invention to provide an implantable pump assembly having an elastic bladder actuator having a variable interior volume, the interior volume varying in accordance with local pressure variations.

It is still another object of the invention to provide an improved, biologically implantable pump assembly having a pumping rate which is a function of local pressure conditions.

It is another object of the invention to provide an implantable pump assembly having an elastic bladder actuator which can be used to administer drugs.

It is another object of the invention to provide an improved method and apparatus for controlling glaucoma including a micropump having an elastic bladder actuator which is implanted into the anterior chamber of the eye.

It is another object of the invention to provide an improved method and apparatus for controlling glaucoma including a micropump where pump operation is controlled in accordance with the sensed ocular pressure.

It is yet another object of the invention to provide an improved, biologically implantable pump assembly having a draining tube with a relatively wide outlet end to disperse the outflow of fluid.

Finally, it is a general object of the invention to provide improved elements and arrangements thereof in an apparatus for the purposes described which is dependable and fully effective in accomplishing its intended purposes.

These and other objects of the present invention will become readily apparent upon further review of the following specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Various other objects, features, and attendant advantages of the present invention will become more fully appreciated as the same becomes better understood when considered in conjunction with the accompanying drawings, in which like reference characters designate the same or similar parts throughout the several views, and wherein:

Fig. 1 is a plan view, partly in section, of the basic structure of the pump assembly of the present invention.

Fig. 2 is a side elevational view, partly in section, of the pump assembly of the present invention showing outward expansion of the pump bladder and the resultant fluid flow.

Fig. 3 is a plan view, partly in section, of the pump assembly of the present invention showing outward expansion of the pump bladder and the resultant fluid flow.

Fig. 4 is a plan view, partly in section, of the pump assembly of the present invention also showing inward deflection of the pump bladder and the resultant fluid flow.

Fig. 5 is a side elevational view, partly in section, of the pump assembly of the present invention showing inward deflection of the pump bladder and the resultant fluid flow.

Fig. 6 is a plan view of the pump assembly of the present invention illustrating an alternative configuration for an effluent conduit.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1 - 4(b), a pump assembly, generally indicated by the numeral 10, is shown. The assembly 10 is of a sufficient size to perform its intended function but the structure is essentially the same regardless of size. Thus, if the assembly 10 is used as an ocular implant to treat glaucoma it would be relatively small, whereas a mechanical application might require a much larger pump assembly 10. The primary actuator of the assembly 10 is the bladder 20, or more specifically, the sidewalls 22 of the bladder shown in the non-deflected, quiescent state in Fig. 1. In accordance with a preferred embodiment of the invention, the bladder 20 is made from an elastic material capable of repeated expansion and contraction without permanent deformation. An elastic polymeric material may be used for this application. The minimum amount of force required to cause inward or outward deflection of the bladder sidewalls is a function of the type and thickness of the elastic material employed, and is chosen in accordance with the anticipated deployment of the pump assembly 10.

For example, in the case of an ocular implant to treat glaucoma, sidewall 22 deflection should occur at a pressure slightly above, or below, normal pressure for the eye. As such, the pump 10 is essentially self regulating, the thickness, and therefore the pressure sensitivity, of the sidewalls 22 being determined using mehtods as would be apparent to one of ordinary skill in the art. Thus, in the event the pressure rises above normal eye pressure, the sidewalls 22 will be deflected inward causing fluid to be expelled outward via a drainage conduit as will be explained in more detail later. The amount of inward deflection of the sidewalls 22 will be directly proportional to the ambient pressure in the implant area, as will

be the amount of fluid displaced. Also, the volume of the bladder 20 is chosen in accordance with the desired functionality and local environment, as would also be apparent to one of skill in the art. In the embodiment shown the assembly 10 includes a bladder 20 which is slightly expanded in its non-flexed state.

The bladder 20 is defined by mutually opposed end portions 26, 28, sidewalls 22, and edge regions 30, providing an essentially seamless construction. Edge regions 30 and end portions 26, 28 may be rigid relative to sidewalls to ensure shape retention. Openings 30, 32 formed in end portions 26, 28 allow for fluid flow into and through an inlet conduit 34 which is affixed within opening 30 in fluid tight relation thereto, into the interior of the bladder 20, which serves as a pumping chamber 36, and out through discharge conduit 38 which is secured in fluid tight relation within end portion 28. A one way check valve 40 includes stop partition 42 having an aperture 43 formed therein, and spherical plug member 44 sized to selectively block fluid flow through the aperture 43, the combination serving to selectively permit fluid flow into the conduit 34 as will be explained in more detail later. Discharge or drainage conduit 38 includes check valve 48 which includes stop partition 50 having an aperture 52 formed therein, and spherical plug member 54 sized to selectively block fluid flow through the aperture 54, the combination serving to selectively permit fluid flow into and through the conduit 38.

Operation of the assembly 10 may be described generally as follows. Once situated for deployment within, e.g., an implant area, the bladder 20, in response to the local pressure, will remain unaffected, as shown in Fig. 1. It should be noted that the assembly 10 may be placed in a liquid environment, in which case the bladder 20 will respond to liquid pressure,

as opposed to air pressure. If the ambient pressure increases, the bladder sidewalls 22 will become downwardly deflected as shown in Figs. 4 and 5. Fluid will flow as indicated by arrows 60 from the bladder 20 into and through discharge conduit 38. Discharge conduit 38 may be connected to an additional conduit (not shown) to pump fluid away from the implant area. The discharge conduit 38 may also include a widened end portion 39 to disperse the effluent material. When the ambient pressure decreases, the bladder sidewalls 22 expand, returning to their original shape by way of stored resilient energy, this causes fluid to be drawn into the bladder or pumping chamber 36 via check valve 40, and conduit 34, as shown in Figs 2 and 3, arrows 62. If the pressure fluctuates, the assembly 10 will fluctuate between the expanded and contracted or compressed state, alternately taking in and expelling fluid from the chamber 36. If used as an implant, the pump may be used to treat glaucoma, for the controlled delivery of drugs, or for an application requiring the use of low powered, implantable pumps.

As stated above, outward expansion of the pump bladder 20 causes fluid to be drawn into the bladder 20. In accordance with one aspect of the invention therefore, the expansion is a function of physical disturbances or pressure fluctuations in the local environment. However, there are circumstances where means for actuating sidewalls 22 would be desirable. For example, in the case of ocular implants, while increasing ocular pressure will most likely result in an approximately linear and proportional inward deflection of sidewalls 22, decreasing ocular pressure may not result in a proportional outward deflection of sidewalls 22 much beyond the quiescent position. Accordingly, it would be desirable to provide a means for causing both inward and outward deflection of the sidewalls to precisely control the intensity and direction of the pumping action. To that end, sidewalls 22 may be

constructed from ionic polymer metal composite (IPMC) synthetic muscles. These synthetic muscles are made from ionic polymeric (polyelectrolyte) gels chemically treated with platinum (IPPC). They exhibit large motion sensing and actuation capabilities in a distributed manner. IPMCs are three-dimensional networks of cross-linked macromolecular polyelectrolytes with internal electrodes that swell, shrink, bend or generally deform, predictably, in an electric field. Conversely, IPMCs are capable of generating an electric field or voltage as a result of being manipulated, the magnitude and polarity of the voltage generated being linearly and directly proportional to the amount and direction of deformation. Thus, direct computer control and monitoring of large expansions and contractions of ionic polymeric gel-noble metal composite muscles by means of a voltage controller and voltmeter has been achieved. The IPMCs require only a few volts for actuation. These muscles can be cut as small as needed and still preserve their functional properties. U.S. Pat. Nos. 5,389,222, issued to Shahinpoor and 6,109,852 issued to Shahinpoor, et al. both disclose exemplary synthetic muscle materials from which diaphragm 20 may be made and are herein incorporated by reference.

An arrangement for controllably applying electrical pulses to the sidewalls 122 is shown in Fig. 6. Electrodes 68, 70 deposited upon or contained within sidewalls 122 are electrically connected to a source of electrical power via leads 72. The voltage or signal applied to electrodes 68, 70 may be provided by an induction coil 74, which, in the event the pump 100 is used as a bio-implant, may be transcutaneously powered by an induction generator or coil 78. A low power alternating voltage may be induced in the coil 74 by adjacent coil 80 which is connected to a suitable low power alternating voltage source 82. A computer or dedicated microprocessor device 84, having a power supply, and a signal

generating and processing means operably connected thereto, can receive electrical signals from, as well as send electrical signals to the pump assembly 100 via voltage source 82 and coils 80 and 82. In accordance with one aspect of the invention, pump 100 and coil 74 may be subcutaneously implanted so that coil 74 can receive pulses from coil 80. When coil 74 is pulsed by electromagnetic fields from coil 80, electrical signals are sent to electrodes 68, 70. The pulsing coil 80 can also receive electromagnetic fields generated by coil 74, the resulting signal may be sent to computer 84 for analysis. Thus, the pump 100 may be interrogated and its pumping action controlled in response to sensed conditions. For example, if coil 74 is fed a low voltage alternating signal via coil 80 by way of mutual induction, a computer 84 may control the signal fed to the coil 74, while monitoring the voltage/current in conductors 72 which are electrically connected to electrodes 68, 70. This arrangement is essentially identical to that discussed in connection with U.S. Patent number 6,589,198, which is herein incorporated by reference. In lieu of an alternating voltage source, power may be applied to leads 72 by way of a relatively large piece of artificial muscle material, which is attached to a source of motive power as is also discussed in U.S. Patent 6,589, 198.

Finally, pump 10, 100 may be manually manipulated to cause fluid flow therethrough. In the case of an ocular implant, ocular pressure may be manually decreased by depressing the sidewalls 22, 122 through the skin, with the resultant pressure being measurable using the arrangement described above.

It is to be understood that the provided illustrative examples are by no means exhaustive of the many possible uses for our invention.

From the foregoing description, one skilled in the art can easily ascertain the essential characteristics of this invention and, without departing from the spirit and scope thereof, can make various changes and modifications of the invention to adapt it to various usages and conditions.

It is to be understood that the present invention is not limited to the sole embodiment described above, but encompasses any and all embodiments within the scope of the following claims: